

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-19 were submitted and were subject to restriction. Claims 1-17 were examined on the merits. Claims 18-19 were withdrawn as being directed to a non-elected embodiment of the invention.

Claims 1, 4-8 and 12-16 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Oetke *et al.* Claims 1-17 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement.

Claims 11, 12, 14, 16 are canceled without prejudice. Claims 1, 13, and 15 are amended. The amendment to claim 1 reciting that the modifying group is "covalently" attached is supported at paragraph [0038], lines 5-6. New claims 20, 21 and 22 are added. Support for claim 20 is found at paragraph [0170], Table 4. Support for claim 21 and 22 is found at paragraph [0198]. Support for claim 23 is found at paragraph 280. No new matter is added by these amendments and additions.

Amendment to the Specification

The specification was amended on page 74, paragraph [0280] to delete the last line of the paragraph which was a typographical error. The last line stated:

"*Squiggly line should be cont'd – with all schemes?".

The deletion of the last line of paragraph [0280] adds no new matter.

Response to Rejections under 35 U.S.C. §102

Claims 1, 4-8, and 12-16 are rejected under 35 U.S.C. §102 as allegedly being anticipated by Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002) ("Oetke").

Claim 1 as amended recites a method of forming a conjugate of a sialic acid moiety covalently functionalized with at least one water-soluble polymer. Oetke does not disclose conjugates of water-soluble polymers or methods of making such conjugates. Since Oetke fails to disclose each element of the claimed invention, claim 1 and its direct and indirect dependents are not anticipated by Oetke. Accordingly, Applicant respectfully requests the withdrawal of the instant rejection.

Response to Rejections under 35 U.S.C. §112

Claims 1-17 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that the basis for this rejection is that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Applicant respectfully traverses this rejection for the reasons set forth below.

On page 7 of the Office Action, the Examiner states that the possible structural variations are limitless to any class of nucleotidyl moiety, activating group, leaving group, water-soluble polymer, therapeutic moiety, detectable label, biomolecule and targeting moiety. Applicant respectfully suggests that the claims, particularly as now amended, do not provide such an unlimited scope. For example, in claim 1, the modified sugar moiety is recited as being a sialic acid moiety. Furthermore, the structural variations in the modifying groups are focused on a water-soluble polymer. These variations are by no means of unlimited scope, because they provide a defined modified sugar and defined modifying groups for the variations and, as illustrated in the accompanying Exhibit A, the term "water-soluble polymer" has an art-recognized meaning. Moreover, the chemical compositions are utilized in a method for producing polypeptide conjugates. Therefore, the recited structures encompass those species that are functional within the claimed method. Undue experimentation is not required to determine whether a particular compound is incorporated into a polypeptide conjugate. The Examiner acknowledges the level of skill in the art is high, and detection and characterization of a polypeptide conjugate is readily accomplished by numerous art-recognized techniques.

Moreover, Applicant maintains that the term "water soluble polymer" is well-established and defined in the art and is not merely a functional description. Entire publications are dedicated to the subject of "water-soluble polymers". See, for example, *Water Soluble Polymers*, Ed. N.M. Bikales (1973), *Chemistry and Technology of Water soluble Polymers*, Ed. C.A. Finch (1983) and *Water-soluble Polymer Applications in Foods*, Ed. A. Nussinovitch (2003). In particular, Applicant respectfully directs the Examiners' attention to Exhibit A, enclosed with this response.

Discussion of Exhibit A

The authors of Exhibit A (Handbook of Polymer Blends, and Composites Volume 3A, Chapter 5, Staikos G, Bokias G and Bumbu GG) state that *“Water soluble polymers” [...]* were recognized as a group in its own right in the 1960s after the publication of a text edited by Davidson and Sittig in 1962 concerned with the sources properties and applications of water soluble polymers [...]” (Emphasis added, Exhibit A, p.135). The authors further explain that *“Water-soluble polymers are classified as [...] natural, semisynthetic (chemically modified natural) and synthetic polymers according to their origin”* (Emphasis added, Exhibit A, p.135). The authors provide examples for each class of water-soluble polymer in Table 5.1 on page 136. Those examples are consistent with Applicant’s examples described in the specification.

Furthermore, the authors state that water-soluble polymers have at least one common structural feature, which is the presence of polar groups that allow the dissolution of water-soluble polymers in water: *“Dissolution of polymers in water is possible only if they contain a polar group”*. The authors also provide exemplary polar groups that are commonly used in water-soluble polymers: *“[...] polar groups, such as an ether oxygen (e.g., PEO, PVME), a hydroxyl (PVAL), an amine (PEI), a carboxylic (PAA, PMAA), an amide (PAAM, PNIPAM), or an ionic group, such as a carboxylate (poly(sodium acrylate)-PNaA), a sulfate (PSSA), or a quaternary ammonium group(PDADMAC)”* (Emphasis added, Exhibit A, p.137, first paragraph).

It is Office policy to issue claims reciting “water-soluble polymer”

Further evidence that the term “water-soluble polymer” is sufficient to meet the written description requirement under U.S.C. §112, first paragraph is the significant number of US patents allowed and issued by the Office in which the term “water-soluble polymer” is used as a claim term. A review of the patent literature reveals a large number of issued U.S. patents that include the term “water-soluble” in the claims. From 1976 to 2007, more than **21,000** patents were issued, which include the term “water-soluble” in the claim section, more than 550 of which were issued in 2007 alone (see, e.g., U.S. Patent No.: 6,010,718, claim 2).

A review of the recently issued patents revealed numerous patents, in which the term “water-soluble polymer” is recited in the claims. A selection of those patents and the applicable claims are summarized, below. Applicant notes that the listed patents include only those patents issued in November and December of 2007 and that the patent literature includes a very large number of additional patents claiming “water-soluble polymer”.

1. U.S. Patent 7,307,141

Claim 2: The apparatus of claim 1, wherein the polymer solution includes a *water-soluble polymer* or an organo-soluble polymer (emphasis added).

2. U.S. Patent 7,306,035

Claim 9: A method as claimed in claim 8 wherein the particles of production chemical are coated with a coating agent selected from *water-soluble polymers* and oil-soluble polymers (emphasis added).

3. U.S. Patent 7,304,041

Claim 9: The nucleic acid ligand of claim 1, wherein the nucleic acid is modified with a *water-soluble polymer* (emphasis added).

Claim 10: The nucleic acid ligand of claim 9, wherein the polymer is polyethylene glycol (emphasis added).

4. U.S. Patent 7,303,756

Claim 7: The method of claim 1 wherein the carrier phase comprises a carrier material comprising a *water-soluble polymer* or a polymer which is soluble in aqueous fluids (emphasis added).

5. U.S. Patent 7,303,704

Claim 1: A method of manufacturing lightweight ceramics, comprising the steps of: A. mixing a powdered glass material, a powdered alkali silicate, and a *water-soluble polymer* according to a fixed proportion to produce a dry substrate; B. adding water to the dry substrate and molding the substrate into a desired shape to produce a molded substrate; C. removing part of the water; and D. heating the molded substrate to a predetermined temperature to form a ceramic; wherein, in the heating step D, oxide and hydroxide in the alkali silicate being used to lower the softening point to the powdered glass material, and when the powdered glass material being in a semi fluid state, air and crystal water brought by the alkali silicate being expanded and forming air bubbles, the *water-soluble polymer* being converted into a gas and forming close pores inside the ceramic, pores with open passages on the surface of the ceramic (emphasis added).

6. **U.S. Patent 7,300,585**

Claim 3: The method of claim 1 wherein treating the thus-treated stream with a second *polymer* to flocculate the precipitate comprises treating the thus-treated stream with a second ***water-soluble polymer*** (emphasis added).

7. **U.S. Patent 7,297,511**

Claim 1: [...] and (b) contacting said truncated glycan with at least one glycosyltransferase and at least one modified sugar donor under conditions suitable for said at least one glycosyltransferase to transfer a modified sugar moiety of said at least one modified sugar donor to said truncated glycan, wherein said modified sugar moiety comprises at least one modifying group which is a ***water-soluble polymer***, thereby forming said covalent conjugate of said interferon alpha peptide (emphasis added).

8. **U.S. Patent 7,297,454**

Claim 8: A method of printing on glossy or semi-glossy coated paper a uniformly stain resistant and glossy image over an entire print surface of the image; said method comprising printing said image with an inkset comprising 1) a colorless ink containing a ***water soluble polymer*** or dispersed latex; wherein said colorless ink is substantially free of colorants, and 2) one or more colored inks [...] (emphasis added).

In conclusion, the term “water-soluble”, and the term “water-soluble polymer” in particular, are used extensively in the claim-sections of issued U.S. patents (especially recently issued patents). Applicant submits that there should be no difference between the term “water-soluble polymer” or the term “water-soluble” as used in the claims of recently issued patents, and Applicant’s use of the same terms. Applicant further submits that because “water-soluble polymer” is a term that is well accepted in the patent literature and routinely considered descriptive by the USPTO, it should be considered descriptive in the context of the currently claimed invention.

The Examiner also states on page 7 of the Office Action that the possible structural variations are limitless to any class of sugar nucleotide. However, as was also discussed in the Interview, the term “nucleotidyl moiety, activating group, leaving group, water-soluble polymer, therapeutic moiety, detectable label biomolecule and targeting moiety.

Partial structure, physical or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function

The Examiner states on page 8 that “[...] the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples..” Applicant respectfully disagrees with the Examiner’s assessment for the following reasons:

As established hereinabove, the term “water-soluble polymer” has an accepted meaning in the art. A person of skill will know that “water-soluble polymer” includes, for example, “poly(amino acids)”, “poly(sialic acid)” and other poly(acids). It is not necessary to provide a detailed chemical structure for a skilled person to determine the structure of a sialyl residue that is modified with another water-soluble polymer, such as a poly(amino acid) moiety (e.g. a polylysine) or a polysialic acid moiety instead of a poly(alkylene oxide) group, because the structures of such polymers are known to those of skill in the art.

For example, the terms “poly(amino acid)”, “poly(ether)”, “poly(acrylic acid)” and “polysaccharide” (e.g., polysialic acid) are each well established in the art, associated with chemical structures and thus not merely functional as suggested by the Examiner.

Because the term “water-soluble polymer” describes a class of polymers with distinct chemical structures and properties, and because the term “water-soluble polymer” is well established and recognized in the art, Applicant has sufficiently described the invention as currently claimed and respectfully ask the Examiner to withdraw the rejection.

Response to Double-Patenting Rejection

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 1-94 of U.S. Patent No. 7,265,085 B2 in view of Oetke, *et al.*, “Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues,” The Journal of Biological Chemistry, 277:6688-6695 (2002).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 112-214 of U.S. PG Pub 20080050772 in view of Oetke, *et al.*, “Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues,” The Journal of Biological Chemistry, 277:6688-6695 (2002).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 1-155 of U.S. Patent No. 7,297,511 in

view of Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 1-113 of U.S. Patent No. 7,226,903 in view of Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 10-32 of U.S. Patent No. 7,214,660 in view of Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 1-107 of U.S. Patent No. 7,179,617 in view of Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002).

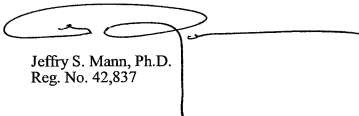
Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 1-94 of U.S. Patent No. 7,173,003 in view of Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double-patenting as allegedly being unpatentable over claims 1-94 of U.S. Patent No. 7,157,277 in view of Oetke, *et al.*, "Versatile Biosynthetic Engineering of Sialic Acid in Living Cells Using Synthetic Sialic Acid Analogues," The Journal of Biological Chemistry, 277:6688-6695 (2002).

Because no claims have been found to be allowable to date, the rejection is necessarily provisional. Applicant will consider traversing the rejections or timely filing an appropriate terminal disclaimer on indication that one or more claim is allowable.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-442-1000.

Respectfully submitted,



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